

REMARKS

Claims 1-5, 7, 8 and 11-16 are pending in the application. Applicants have amended claims 1 and 11. No new matter is introduced. Accordingly, entry and consideration of this Amendment is respectfully requested.

The Examiner has rejected claims 1-5, 7, 8 and 11-16 under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter. Specifically, the Examiner rejects the recitation of an electrode that contacts a surface of tissue directly, and a compliant material that secures the contact between the electrode and the tissue surface, based on the ground that tissue is non-statutory subject matter. The Examiner has suggested amending the foregoing recitations to an electrode that is adapted to contact a surface of tissue and a compliant material that is adapted to secure the contact between the electrode and the tissue surface. Applicants have amended independent claims 1 and 11, accordingly. Thus, the rejection of claims 1-5, 7, 8 and 11-16 under 35 U.S.C. §101 as directed to non-statutory subject matter is overcome.

Based on the same reason, the Examiner has rejected claims 1-5, 7, 8 and 11-16 under 35 U.S.C., §112 as allegedly failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In view of the above amendments of claims 1 and 11, this rejection is overcome.

The Examiner has rejected claims 1-5, 7, 8 and 11-16 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 6,932,816 to Phan (hereafter "Phan") in light of U.S. Patent No. 5,277,201 to Stern et al. (hereafter "Stern"). The rejection is respectfully traversed.

Claim 1 recites an applicator for creating a lesion in tissue. The applicator comprises, *inter alia*, a first rigid or semi-rigid support member, a first compliant material coupled to the first support member, a first passage in communication with the first compliant material for infusing a medium into the compliant material to inflate the compliant material, and

at least one electrode for conducting energy to a surface of the tissue. Significantly, the electrode is adapted to contact the tissue surface directly and the compliant material is adapted to secure the contact between the electrode and the tissue surface by the inflation thereof.

Applicants' independent claim 11, as amended, recites an applicator for creating lesions in tissue. The applicator comprises, *inter alia*, a first rigid or semi-rigid support member, means for conducting energy to a surface of the tissue mounted to the first support member, and means for varying the distance between the means for conducting energy to the surface of the tissue and the surface. Significantly, the energy conducting means is adapted to contact the tissue surface directly, and the means for varying the distance between the energy conducting means and the tissue surface is adapted to secure the contact between the energy conducting means and the tissue surface.

Turning to the prior art, Phan discloses an energy transmission assembly used to coagulate tissue. Specifically, as shown in Figs. 13 and 14 of Phan, the energy transmission assembly (132) comprises a cylindrical base member (134), a slot (128) for fixedly accommodating an energy transmission device (108), and a tissue cooling apparatus (154). The energy transmission device (108) comprises an electrode to apply energy to the tissue to be coagulated. The tissue cooling apparatus (154) comprises an outer casing (156), which contacts the tissue. The outer casing (156) is secured to the base member (134) and disposed over the electrode such that to define a fluid transmission space between the outer casing (156) and the electrode, for an electrically conductive ionic fluid to run from one end of the base member to the other end of the base member.

Specifically, the outer casing (156) is a nanoporous casing having pores to allow the transport of ions contained in the fluid through the casing and into contact with the tissue. Thus, when the electrode transmits energy into the ionic fluid, the ionic fluid establishes an

electrically conductive path between the electrode and the tissue being coagulated. Therefore, there is no need for an electrically conductive metal surface at the tissue interface (see Lines 56-61, Col. 13 of Phan). Further, Phan discloses that “heat from the tissue being coagulated is transferred to the ionic fluid to cool the tissue while energy is transferred from an electrode or other energy transmission device to the tissue” (see Lines 61-65, Col. 11 of Phan).

Therefore, the entire configuration of the outer casing, the electrode within the casing, and the electrically conductive ionic fluid running through the fluid transmission space defined by the outer casing, functions to provide an electrically conductive path between the energy transmission device and the tissue to eliminate the need of an electrically conductive metal surface and to simultaneously absorb the heat applied to the tissue being coagulated.

Stern discloses an endometrial ablation apparatus for the destruction of the inner lining of body organs. Specifically, the apparatus comprises a balloon and electrodes disposed on the inner or the outer surface of the balloon. After the apparatus is inserted into a body organ, the balloon is inflated with fluids, to effect electrical contact of the electrodes with the endometrial lining.

In the Office Action, the Examiner asserts that Phan discloses all the element of claim 1 except that the electrode of Phan is disposed inside the outer casing instead of located on the outer surface of the outer casing to directly contact the tissue surface. The Examiner further asserts that Stern discloses that the electrode can be disposed on the outer surface of the balloon. Therefore, the Examiner has reached the conclusion that it would have been obvious for a person of ordinary skill in the art to modify Phan in view of Stern, by way of disposing the electrode on the outer surface of the outer casing, to arrive at the combination of features recited by claim 1 of the present application. Applicants respectfully do not agree in this regard.

As stated above, Phan discloses a configuration wherein the electrically conductive fluid is disposed between the outer casing and the electrode. Phan further teaches that this configuration is for the purposes of providing an electrically conductive path between the electrode and the tissue without the need of a metal interface and further providing a cooling fluid running through the fluid transmission space between the electrode and the tissue. Thus, in order to fulfill the above purposes, it is necessary and indispensable to provide an outer casing covering the electrode and an electrically conductive fluid between the electrode and the outer casing. Thus, the electrode does not contact the tissue directly and the outer casing does not secure the contact between the electrode and the tissue.

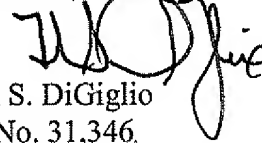
In stark contrast, claim 1 recites that the electrode is adapted to contact the tissue surface directly and the compliant material is adapted to secure the contact between the electrode and the tissue surface by the inflation thereof. Thus, Phan explicitly teaches away from the present invention, recited by claim 1.

Therefore, even assuming, *arguendo*, that Stern teaches the disposition of an electrode on the outer surface of the outer casing, it would not be reasonable for a person of ordinary skill in the art to modify Phan by altercating the disposition of the electrode from inside the casing to the outer surface of the outer casing, which is a blatant contradiction with the underlying functionality of the configuration of Phan wherein the outer casing covers the electrode and the electrically conductive fluid runs between the casing and the electrode.

As well established, “it is improper to combine references where the references teach away from their combination”. *In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Thus, Applicants respectfully submit that there is no proper reasoning supported in any of the references to modify Phan in view of Stern to arrive at the combination of features recited by claim 1, since Phan teaches away from the invention.

Thus, in view of the foregoing amendments and remarks, it is firmly believed that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. DiGiglio', written over the printed name.

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